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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/296,534	04/22/1999	ROBERT HALLOWITZ	BIOTI-7	8502

33449 7590 12/17/2003

BIO-TECH IMAGING, INC.  
5711 INDUSRTY LANE UNIT 31  
FREDERICK, MD 21704

EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/296,534

Applicant(s)

HALLOWITZ ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15, 16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The amendment and response filed on 9-25-2003 are acknowledged. Claims 1, 18 and 19 have been amended. Claims 20-22 have been added. Claim 17 remains withdrawn from consideration. Claims 1-13, 15-16 and 18-22 are currently under examination.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-27-2003 has been entered.

#### ***Objections Withdrawn***

##### ***Priority***

The objection to the specification with regard to the priority statement is withdrawn. Applicant has stated that no priority date is being claimed.

##### ***Oath/Declaration***

The objection based on the oath or declaration being defective is withdrawn. Since Applicant is claiming no priority date, the declaration does not need to be modified.

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***Claim Rejections Withdrawn***

The rejection of claims 18-19 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "cell population" is withdrawn in light of the amendment thereto.

The rejection of claims 18-19 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "capable of" is withdrawn in light of the amendment thereto.

The rejections of claims 1-13, 15-16 and 18-19 under 35 U.S.C. 103(a) as being unpatentable over Chun et al. (Nature Vol. 387, pages 183-188, May 1997) in view of Chun et al. (Nature Medicine, Vol. 1, No. 12, pages 1284-1290, December 1995) and Essex et al. (U.S. Patent 4,725,669) and the rejection of claim 13 19 under 35 U.S.C. 103(a) as being unpatentable over Chun et al. (Nature Vol. 387, pages 183-188, May 1997) in view of Chun et al. (Nature Medicine, Vol. 1, No. 12, pages 1284-1290, December 1995) and Essex et al. (U.S. Patent 4,725,669) and Chun et al. (Journal of Experimental Medicine, Vol. 188 No. 1, July 6, 1998 pages 83-91) are withdrawn in light of the amendments thereto and Applicant's arguments.

***Claim Rejections Maintained and New Grounds of Rejection***

***35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 15-16 and 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention is maintained for reasons set forth in the previous Office action in the rejection of claims of record.

Claims 1, 18 and 19 still fail to recite active method steps that read on the preamble of the claims. The amended claims recite the phrase “whereby said latent viral load is the determined number of cells”. It is unclear how this is correlated to the viral load **in a host** or even if such a correlation can be made.

Claims 1, 18 and 19 are still incomplete because the preamble of the amended claim recites “A method of determining latent viral load **in a host**” but there is no language that serves to correlate the result of “determining the number of cells expressing gp120” with “determining viral load”. As outlined above, the amended claims recite the phrase “whereby said latent viral load is the determined number of cells”. It is unclear how this is correlated to the viral load **in a host** or even if such a correlation can be made.

The amended claims still do not provide the methods by which a correlation between the number of stimulated cells that express gp120 and the latent viral load in a host infected with HIV-1. Moreover, it should be noted that the number of said cells expressing gp120 would increase over time since the HIV-1 in said cells is no longer “latent” and said virus has been stimulated into its normal replication cycle.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 15-16 and 18-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detecting and quantifying latent HIV-1 infections in various purified mononuclear cell populations, does not reasonably provide enablement for methods of determining the latent viral load **in an infected host**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant claims are drawn to methods of determining the latent HIV-1 load in infected individuals (i.e. quantifying all latently infected cells present in an HIV-1 infected host). HIV-1 infects not only many cell types (e.g. dendritic cells, monocytes, macrophages and various T lymphocyte subsets) but also hematopoietic progenitor cells and other cell types (see Fields Virology, Third Edition, Lippincott-Raven Publishers, Philadelphia PA, 1996, pages 1953-1957). The specification discloses methods of determining the number of latently infected cells in a single purified cell population but is silent on how such a determination can be correlated to the *in vivo* status of an infected host where a multitude of cell populations are actively (and latently) infected at any given time. The specification does not disclose all the cell types within a human host that are susceptible to HIV-1 infection and is equally silent on what agents would be used to stimulate a given cell population (other than mononuclear cells). To determine the viral load of an individual, one must determine the number of latently infected cells in all cell populations (types). The specification does not disclose the methodologies that would allow this to be accomplished. Consequently one of ordinary skill in the art would not be able to use the instant

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invention since the specification is silent on how the detection of gp120 in a single purified cell population can be correlated to the viral load **in a host** or even if such a correlation can be made.

*Conclusion*


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
NITA MINNIFIELD  
PRIMARY EXAMINER  
12/19/03

Robert A. Zeman  
December 10, 2003